

Atty Dkt. No.: CALD-007
USSN: 10/029,407

REMARKS

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-23, the only claims pending and currently under examination in this application.

Claims 1, 6, 11 and 19 have been amended to specify that an NSAID is the sole active agent in the topical formulation. Support for these amendments can be found in the specification, e.g., at page 4, lines 19-20.

As no new matter has been added by the above amendments, the Applicants respectfully request the entry thereof.

Rejections under 35 U.S.C. §102(b)

Claims 1-18 have been rejected under 35 U.S.C. §102(b) as anticipated by Meyer et al. (WO 97/17978).

As described above, the claims have been amended to specify that an NSAID is the sole active agent in the topical formulation. Meyer et al. teach pharmaceutical compositions that include an NSAID and nitrous oxide. The Applicants respectfully submit that nitrous oxide is an active agent and in fact Meyer et al. specifically acknowledge that nitrous oxide is an active agent. For example at page 4, lines 22-23 Meyer et al. state "In Applicant's PCT patent application PCT/EP93/01405...and co-pending applications...and its South African counterpart...it disclosed dermatological compositions comprising **nitrous oxide as an active ingredient** in compositions..." (Emphasis added) Accordingly, Meyer et al. do not teach a topical formulation having an NSAID as the sole active agent as claimed in the subject claims, but rather teach pharmaceutical compositions that include at least two active agents: (1) an NSAID, and (2) nitrous oxide.

For at least this reason, the Applicants respectfully request that this rejection be withdrawn.

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Rejections under 35 U.S.C. §103(a)

Claims 19-23 have been rejected under 35 U.S.C. §103(a) as obvious over Meyer et al. (WO 97/17978).

Claim 19, and the claims the depend therefrom, specify a kit that includes a topical formulation having an NSAID as the only active agent. As described above, Meyer et al. specifically teach compositions that include at least two active agents. Furthermore, the claims specify instructions for using a topical formulation having an NSAID as the only active agent in a method according to Claim 1. Since Meyer et al. fail to teach or suggest the claimed formulation, Meyer et al. also fail to teach or suggest instructions for using such a formulation in a method according to Claim 1.

For at least these reasons, Meyer et al. fail to teach or suggest all of the claimed limitations. Accordingly, a proper *prima facie* case of obviousness cannot be made. As such, the Applicants respectfully request that this rejection be withdrawn.

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CONCLUSION


In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance. The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, Order No. CALD-007.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date:

4-23-04

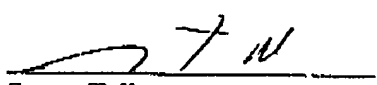
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